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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/027,736 | 12/19/2001 | Leonard G. Presta | 11669.92US01 | 9756 |
| 23552 | 7590 | 12/29/2003 | | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | EXAMINER BELYAVSKYI, MICHAEL A | |
| | | | ART UNIT 1644 | PAPER NUMBER 12 |
| DATE MAILED: 12/29/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,736

Applicant(s)

PRESTA ET AL.

Examiner

Michail A Belyavskyi

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-90 are pending.

Restriction Requirement

- I. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-9, 11, 14, 15-20 and 75-90, drawn to an isolated nucleic acid sequences that encodes a non-human primate Fc receptor polypeptide, vectors, and host cells classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
 - II. Claims 10, 12 and 13 drawn to a method for obtaining a nucleic acid sequences encoding an Fc receptor polypeptide, classified in Class 530, subclass 91.2.
 - III. Claims 21-28 and 37-43, drawn to an isolated polypeptide, classified in Class 530 subclasses 300 and 350.
 - IV. Claims 29-36, drawn to drawn to a fusion protein, comprising a heterologous polypeptide joined to a Fc receptor polypeptide fragment, classified in Class 530, subclass 350
 - V. Claims 44-51 and 54-58, drawn to a method for evaluating at least one biological property of an Fc region, wherein biological property is the binding affinity of the Fc region, comprising contacting an isolated non-human primate Fc receptor polypeptide with an Fc region containing molecule, classified in Class 435, subclass 7.1.
 - VI. Claims 44-50, 52 and 54-58, drawn to a method for evaluating at least one biological property of an Fc region, wherein biological property is the toxicity of the Fc region containing molecule, comprising contacting an isolated non-human primate Fc receptor polypeptide with an Fc region containing molecule, classified in Class 435, subclass 7.1 and 325.
 - VII. Claims 44-50, 53 and 54-58, drawn to a method for evaluating at least one biological property of an Fc region, wherein biological property is the half-life of the Fc region containing molecule, comprising contacting an isolated non-human primate Fc receptor polypeptide with an Fc region containing molecule, classified in Class 435, subclass 7.1.

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- VIII. Claims 59-65, drawn to a method for evaluating at least one biological property of an Fc region, comprising contacting an Fc region containing molecule with a cell transformed with an isolated nucleic acid, classified in Class 435, subclasses 6, 252.1, 326.
- IX. Claims 66-69, drawn to a method for identifying an agent that has an increase affinity for at least one cynomolgus Fc receptor, comprising determining the binding affinity of the agent to at least one cynomolgus Fc receptor polypeptide associated a polypeptide with an ITAM region, classified in Class 435, subclasses 6, 7.1.
- X. Claims 70-71, drawn to a method for identifying an agent that has an altered affinity for at cynomolgus Fc receptor with an ITIM region, comprising determining the binding affinity for the agent to at least one cynomolgus Fc receptor polypeptide classified in Class 435, subclasses 6, 7.1.
- XI. Claims 72-74, drawn to a method for identifying an agent with increase affinity for a cynomolgus Fc receptor polypeptide with an ITAM region and decrease affinity for a cynomolgus Fc receptor polypeptide with an ITIM region, comprising determining the binding affinity for the agent to at least one cynomolgus Fc receptor polypeptide associated with an ITAM region, classified in Class 435, subclasses 6, 7.1.

2. Groups I, III and IV are different products. Nucleic acids, polypeptides, and fusion protein differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct.

3. Groups II and V-XI are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

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5. In addition, each group reads on and or uses patentable **distinct sequences**. Each sequence is patentably distinct because they are unrelated sequences and further restriction is applied to each group. For each elected group drawn to or using polypeptide sequence, the Applicant must further elect a single amino acid sequence. For each elected group drawn to or using nucleotide sequence, the Applicant are required to elect a single sequence (See MPEP 803.04). In view of limited office resources , only a single nucleic or amino acid sequence will be examined in this application. In addition, to the specific selected sequence, those sequences which are patentably indistinct from the selected sequences will be also examined.

Examination will be restricted to only one elected sequences.

Species Election

6. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. If Group II is elected, applicant is required to elect a specific method for obtaining a nucleic acid sequences , wherein one specific forward and a reverse primer set is selected from the group recited in claim 10.

These species are distinct because a specific method for obtaining a nucleic acid sequences , wherein one specific forward and a reverse primer set is selected from the group recited in claim 10 are differ with respect to specific primer set. Furthermore, the examination of specific one specific forward and a reverse primer set selected from the group recited in claim 10 in the methods for obtaining a nucleic acid sequences, would require different searches in the scientific literature.

8. If one of the Groups V-VII or IX is elected, Applicant is required to elect a specific method for evaluating one biological property of an Fc region, or a specific method for identifying an agent that has an increase affinity for at least one cynomolgus Fc receptor, wherein the non-human primate receptor polypeptide is selected from the group recited in claims 49 or 69.

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These species are distinct because specific method for evaluating one biological property of an Fc region , or a specific method for identifying an agent that has an increase affinity for at least one cynomolgus Fc receptor, wherein the non-human primate receptor polypeptide is selected from the group recited in claims 49 or 69 are differ with respect to non-human primate receptor polypeptide. Furthermore, the examination of specific non-human primate receptor polypeptide in the methods for evaluating one biological property of an Fc region, or in a method for identifying an agent that has an increase affinity for at least one cynomolgus Fc receptor would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

A telephone call was made to Katherine Kowalchuk on 12/05/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
December 22, 2003


CHRISTINA CHAN
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